

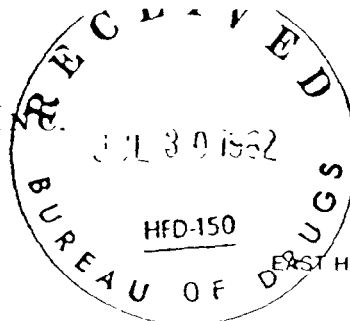


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SANDOZ, INC.



PHARMACEUTICAL DIVISION  
DRUG REGISTRATION &  
REGULATORY AFFAIRS



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July 29, 1982

William Gyarfas, M.D., Director  
Division of Oncology and Radio-  
pharmaceutical Drug Products  
Bureau of Drugs, HFD-150  
Att: Document Control Room  
17B-34  
5600 Fishers Lane  
Rockville, Maryland 20857

NDA #18-772  
Sandimmune™ (Cyclosporine)  
Concentrate for Infusion  
Original New Drug Application  
NDA Sections 2&3, 10&16  
FDA Classification: Category 1A

Dear Dr. Gyarfas:

In accordance with 21 CFR 314.1 and Section 505(b) of the Federal Food, Drug and Cosmetic Act, Sandoz Pharmaceuticals herewith submits, in triplicate, NDA Sections 2&3, 10 and 16 (i.e., nonclinical summary/full reports/literature and GLP Statement) for Sandimmune™ (Cyclosporine) Concentrate for Infusion. By prior agreement, permission has been granted to file this new drug application sequentially.

NDA Sections 6,7,8,9 and 15 (i.e., manufacturing and controls data, environmental impact analysis report, drug samples) were submitted on April 22, 1982 at which time NDA number 18-772 was assigned. The remaining NDA clinical/statistical/miscellaneous sections will be submitted in October 1982.

Sandoz, Inc., considers the information contained in this submission to be confidential.

Sincerely,

SANDOZ PHARMACEUTICALS

Richard J. Raffa  
Senior Project Coordination  
Manager

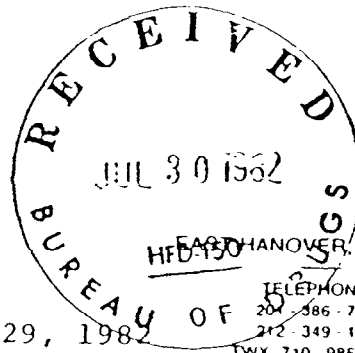
RJR:vb  
Submitted in triplicate  
Attachment: NDA Volumes 2.1-2.2 (inclusive)

cc: Mr. Stanley A. Stringer, Chief  
Product Coordination Staff (HFD-105)

SANDOZ, INC.



PHARMACEUTICAL DIVISION  
DRUG REGISTRATION &  
REGULATORY AFFAIRS



July 29, 1982

William Gyarfas, M.D., Director  
Division of Oncology and Radio-  
pharmaceutical Drug Products  
Bureau of Drugs, HFD-150  
Att: Document Control Room  
17B-34  
5600 Fishers Lane  
Rockville, Maryland 20857

NDA #18-773  
Sandimmune™ (Cyclosporine)  
Oral Solution  
Original New Drug Application  
NDA Sections 2&3, 10&16  
FDA Classification: Category 1A

Dear Dr. Gyarfas:

In accordance with 21 CFR 314.1 and Section 505(b) of the Federal Food, Drug and Cosmetic Act, Sandoz Pharmaceuticals herewith submits, in triplicate, NDA Sections 2&3, 10 and 16 (i.e., nonclinical summary/full reports/literature and GLP statement) for Sandimmune™ (cyclosporine) Oral Solution. By prior agreement, permission has been granted to file this new drug application sequentially.

NDA Sections 6,7,8,9 and 15 (i.e., manufacturing and controls data, environmental impact analysis report, drug samples) were submitted on April 22, 1982 at which time NDA number 18-773 was assigned. The remaining NDA clinical/statistical/miscellaneous sections will be submitted in October 1982.

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Sincerely,

SANDOZ PHARMACEUTICALS

Richard J. Raffa  
Senior Project Coordination  
Manager

RJR:vb  
Submitted in triplicate  
Attachment: NDA Volumes 2.1-2.17 (inclusive)

cc: Mr. Stanley A. Stringer, Chief  
Product Coordination Staff (HFD-105)